

Informed Consent

Screening Number: _____

Random Number: _____

Sponsor: Plastic Surgery, Xijing Hospital

Version Number: 2.0

Version Date: Dec 08, 2017

Project name:

Comparative study on the clinical efficacy of golden microneedles and 1565nm non-ablative lattice laser in the treatment of eyelid pouches

Possible benefits of participating in the study:

Benefits to the subject: improvement of eyelid pouch, skin texture, skin relaxation, etc.
Benefits for social groups: Evaluation of safety and effectiveness of non-invasive treatment for patients with BLEs.

Possible risks Complications and preventive treatment:

Possible risks	Prevention and treatment
BLEs asymmetry	Bilateral treatment plan interchanged 3 times, followed up for 4 weeks and 12 weeks; severe cases of surgery pain
Pain	Local 5% compound lidocaine cream film sealed surface anesthesia, if necessary neurological stagnation
Swelling, Bruising	Cold pack for 30 minutes before and after treatment. Keep the head high for at least 3 days after treatment.
Exudation,punctate hemorrhage	Compression to reduce bleeding, external medical repair accessories to promote skin repair, reduce exudation.
Pigment changes	Apply broad-spectrum sunscreen if necessary oraling VC, VE ect.

Who should I contact if I have questions or difficulties?

If you have any questions about this study, or if you have any discomfort during the study, you can always contact your research doctor: Name: Wenjie Dou . Phone: +86_182 0926 1917 _Address: Plastic Surgery, Xijing Hospital _.

If you have any questions about your rights as a research subject, please contact:

Ethics Committee of Xijing Hospital, Tel: 029-84771794.

Informed Consent Statement Subject

Informed Consent Statement:

The research physician has informed me of the research background, purpose, procedures, risks, and benefits of this study, and I have also read the written information. I have read this informed consent and agree to participate in this study. I have also been told who to contact when I have questions or want further information. I understand that I can withdraw from the study at any time and that my future treatment will not be affected by this. By signing this informed consent, I agree that my physiological and demographic data can be used under the conditions described in this informed consent. I agree that this informed consent form will be made in duplicate, signed by me and the research doctor, and both parties will keep one copy.

Subject name: _____

Subject signature: _____ (block letters)

Date of signature: _____

Research doctor's notification statement:

I have informed the subject "Gold microneedles and 1565nm non-ablative "Comparison of the clinical efficacy of sexual lattice laser in the treatment of blepharoplasty", the research background, purpose, steps, risks and benefits of the project, giving him / her enough time to read the informed consent, discuss with others, and answer its related questions

Questions from the study; I have informed the subject of their contact information when they encounter a problem; I have informed the subject that they can withdraw from the study at any time during the study without any reason.

Research doctor's name: _____

Research doctor's signature: _____ (block letters)

Signature date: _____